



Food and Drug Administration
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January 16, 2015

BM Korea Company, Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Incorporated
2651 East Chapman Avenue, Suite 110
Fullerton, California 92831

Re: K143006

Trade/Device Name: GUARDIAN-SG Inflatable Bone Expander System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: October 10, 2014
Received: October 20, 2014

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K143006

Device Name

GUARDIAN-SG Inflatable Bone Expander System

Indications for Use *(Describe)*

The GUARDIAN-SG Inflatable Bone Expander System is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: January 15, 2015

1. Applicant / Submitter:

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2. Submission Correspondent

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3. Device:

Proprietary Name – GUARDIAN-SG Inflatable Bone Expander System
Common Name – Inflatable Bone Tamp
Classification Name – Arthroscope
Cement, bone, vertebroplasty

4. Predicate Device:

GUARDIAN Inflatable Bone Expander System by BM Korea, K111593
Kyphon Inflatable Bone Tamp by Medtronic Inc., K981251

5. Product Code & Regulation Number:

HRX, NDN
21 CFR 888.3027

6. Description:

The GUARDIAN-SG Inflatable Bone Expander System (IBES) is designed to reduce spinal compression fracture and restore sagittal alignment. By creating a space in the vertebral body to facilitate the insertion of bone cement and using cement dispensing plunger, the major benefits of GUARDIAN-SG IBES are the significant reduction in back pain and increase patient's functional abilities, allow a return to the previous level of activity.



The GUARDIAN-SG IBES components are Inflatable Bone Tamp (balloon catheter, compressor) and accessory kit. And balloon catheter's main components are the shaft, Y-hub and the inflatable balloon located at the distal tip and inflatable balloon is covered maximum 0.03g of silicone fluid to enhance lubricity when the balloon catheter is inserted in the cannula. Radiopaque markers located at the distal and proximal end of deflated working surface allow fluoroscopic visualization of the deflated balloon catheter during positioning.

The Balloon catheter, compressor and the accessory kit are supplied sterile and disposable use.

7. Indication for use:

The GUARDIAN-SG Inflatable Bone Expander System is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

8. Non-Clinical Testing:

The GUARDIAN-SG Inflatable Bone Expander System met the specifications and performance characteristics and is substantially equivalent to the predicate devices. The testing included functional, such as balloon compliance, deflation time, insertion / withdraw force and fatigue testing as well as mechanical testing, such as tensile strength.

9. Substantial Equivalence:

The GUARDIAN-SG Inflatable Bone Expander System has the equivalent device characteristics as the predicate devices; intended use, material, design and use concept are similar.

Based on the comparison of intended use and technical features, the GUARDIAN-SG Inflatable Bone Expander System is substantially equivalent to the predicate devices.

10. Conclusions:

Based on the information provided in this premarket notification, BM KOREA Co., Ltd. concludes that the GUARDIAN-SG Inflatable Bone Expander System is substantially equivalent to predicate devices as described herein.